PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE sperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number Application Number 10/766,124 Filing Date TRANSMITTAL January 28, 2004 First Named Inventor **FORM** Jane Hirsh Art Unit 1615 **Examiner Name** Thurman K. Page (to be used for all correspondence after initial filing) Attorney Docket Number **CP 108** Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance Communication to TC ✓ Drawing(s) Fee Transmittal Form Appeal Communication to Board Licensing-related Papers Fee Attached of Appeals and Interferences Appeal Communication to TC Petition (Appeal Notice, Brief, Reply Brief) Amendment/Reply Petition to Convert to a **Proprietary Information** After Final Provisional Application Power of Attorney, Revocation Status Letter Change of Correspondence Address Affidavits/declaration(s) Other Enclosure(s) (please Identify Terminal Disclaimer below): Extension of Time Request two (2) pages of PTO-1449; sixteen (16) Request for Refund **Express Abandonment Request** references; return postcard CD, Number of CD(s)\_ Information Disclosure Statement Landscape Table on CD Certified Copy of Priority Remarks Document(s) Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name Pabst Patent Group LLP Signature Printed name Tiffany B. Salmon Reg. No. Date 55.589 March 8, 2005 CERTIFICATE OF TRANSMISSION/MAILING I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below: Signature Date Ronna Berman Typed or printed name

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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work Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number TRADEME Complete if Known Effective on 12/08/2004. rsuant to the Consolidated Appropriations Act, 2005 (H.R. 4818). 10/766,124 Application Number FEE TRANSMIT Filing Date January 28, 2004 For FY 2005 Jane Hirsh First Named Inventor Thurman K. Page **Examiner Name** Applicant claims small entity status. See 37 CFR 1.27 Art Unit 1615 TOTAL AMOUNT OF PAYMENT (\$) 0.00**CP 108** Attorney Docket No. METHOD OF PAYMENT (check all that apply) Check Credit Card None Other (please identify): Money Order ✓ Deposit Account Deposit Account Number: 50-3129 Deposit Account Name: Pabst Patent Group LLP For the above-identified deposit account, the Director is hereby authorized to: (check all that apply) Charge fee(s) indicated below, except for the filing fee Charge fee(s) indicated below Charge any additional fee(s) or underpayments of fee(s) ✓ Credit any overpayments under 37 CFR 1.16 and 1.17 WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. **FEE CALCULATION** 1. BASIC FILING, SEARCH, AND EXAMINATION FEES **FILING FEES** SEARCH FEES **EXAMINATION FEES Small Entity Small Entity Small Entity** Fees Paid (\$) **Application Type** Fee (\$) Fee (\$) Fee (\$) Fee (\$) Fee (\$) Fee (\$) 200 300 500 Utility 150 250 100 200 100 100 50 130 65 Design 200 300 160 80 Plant 100 150 500 600 300 150 250 300 Reissue Provisional 200 100 0 0 0 0 **Small Entity** 2. EXCESS CLAIM FEES Fee (\$) Fee (\$) **Fee Description** Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent 50 25 Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent 200 100 180 Multiple dependent claims **Multiple Dependent Claims** Fee Paid (\$) **Extra Claims** Fee (\$) **Total Claims** Fee Paid (\$) Fee (\$) <u>28</u> - 28 or HP = HP = highest number of total claims paid for, if greater than 20 Extra Claims Fee (\$) Fee Paid (\$) Indep. Claims 3 - 3 or HP = 0 HP = highest number of independent claims paid for, if greater than 3 3. APPLICATION SIZE FEE If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). Number of each additional 50 or fraction thereof Fee Paid (\$) **Extra Sheets Total Sheets** (round up to a whole number) x - 100 = Fees Paid (\$) 4. OTHER FEE(S) Non-English Specification, \$130 fee (no small entity discount) SUBMITTED BY Registration No. Telephone (404) 879-2153 55,589

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

(Attorney/Agent)

Signature

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Date March 8,2005



### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Jane Hirsh, Alison B. Fleming, and Roman V. Rariy

Serial No.: 10/766,124 Art Unit: 1615

Filed: January 28, 2004 Examiner: Thurman K. Page

For: MULTIPARTICULATE COMPOSITIOS OF MILNACIPRAN FOR ORAL

**ADMINISTRATION** 

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit a Supplemental Information Disclosure Statement, including two (2) pages of Form PTO-1449, copies of the sixteen (16) documents cited therein.

It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 50-3129.

U.S.S.N.: 10/766,124 Filed: January 28, 2004

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT



# **U.S. Patent Applications**

Number	<b>Publication Date</b>	<b>Applicant</b>	Class/Subclass
2004/0228830	11-18-2004	Hirsh, et al.	424/78.12

### **U.S. Patents**

Issue Date	<u>Patentee</u>	Class/Subclass
08-22-1972	Unger, et al.	260/234
03-17-1987	Becker, et al.	524/801
09-08-1987	Banerjee	514/449
07-11-1989	Illum	424/455
07-03-1990	Leung, et al.	424/59
03-12-1991	Kogan, et al.	424/79
06-25-1991	Eichel, et al.	424/458
12-10-1991	Malkowska, et al.	424/497
01-04-1994	Chang	424/426
03-22-1994	Chang, et al.	424/422
11-29-1994	Umemoto, et al.	424/78.1
10-19-1999	Oshlack, et al.	424/456
11-09-1999	Eichman	424/78.12
09-03-2002	Robinson, et al.	514/17
	08-22-1972 03-17-1987 09-08-1987 07-11-1989 07-03-1990 03-12-1991 06-25-1991 12-10-1991 01-04-1994 03-22-1994 11-29-1994 10-19-1999 11-09-1999	08-22-1972       Unger, et al.         03-17-1987       Becker, et al.         09-08-1987       Banerjee         07-11-1989       Illum         07-03-1990       Leung, et al.         03-12-1991       Kogan, et al.         06-25-1991       Eichel, et al.         12-10-1991       Malkowska, et al.         01-04-1994       Chang         03-22-1994       Chang, et al.         11-29-1994       Umemoto, et al.         10-19-1999       Oshlack, et al.         11-09-1999       Eichman

## **Publications**

ICHIKAWA, et al., "Use of ion-exchange resins to prepare 100  $\mu$ m-sized microcapsules with prolonged drug-release by the Wurster process" *International Journal of Pharmaceutics* 216:67-76 (2001).

U.S.S.N.: 10/766,124

Filed: January 28, 2004

SUPPLEMENTAL INFORMATION

DISCLOSURE STATEMENT

Remarks

This statement should not be interpreted as a representation that an exhaustive search has

been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an

independent evaluation of the cited art to determine its relevance to the subject matter of the

present application. Applicants are of the opinion that their claims patentably distinguish over

the art referred to herein, either alone or in combination.

Respectfully submitted,

Tiffany B. Salmon

Reg. No. 55,589

Dated: March 8, 2005

PABST PATENT GROUP LLP

400 Colony Square, Suite 1200

1201 Peachtree Street

Atlanta, Georgia 30361

(404) 879-2153 (Telephone)

(404) 879-2160 (Fax)

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K	<b>7.</b>	at of			Group Art Unit	1615
	RADEN	HELT GREEN			Examiner Name	Thurman K. Page
	heet	1	of	2	Attorney Docket Number	CP 108

		T 110 D 1 1 D 1	U.S. PATENT DOCUM		
Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	•	Number Kind Code <sup>2</sup> (if known)			
		2004/0228830	Hirsh, et al.	11-18-2004	
		3,686,164	Unger, et al.	08-22-1972	
		4,650,827	Becker, et al.	03-17-1987	
	•	4,692,462	Banerjee	09-08-1987	
	4,847,091 4,938,951		Illum	07-11-1989	
			Leung, et al.	07-03-1990	
		4,999,189	Kogan, et al.	03-12-1991	
		5,026,559	Eichel, et al.	06-25-1991	
		5,071,646	Malkowska, et al.	12-10-1991	
		5,275,820	Chang	01-04-1994	
		5,296,228	Chang, et al.	03-22-1994	
		5,368,852	Umemoto, et al.	11-29-1994	
		5,968,551	Oshlack, et al.	10-19-1999	
		5,980,882	Eichman	11-09-1999	
		6,444,647	Robinson, et al.	09-03-2002	

Examiner Cite No.1	F	oreign Patent Doo	cument	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T⁵	
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

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<u> </u>	2005 (Sp)	•		Filing Date	January 28, 2004	
	84			First Named Inventor	Jane Hirsh	
VR.	The Charles			Group Art Unit	1615	
(use as many sheets as necessary)		Examiner Name	Thurman K. Page			
Sheet	1 2	of	2	Attorney Docket Number	CP 108	

		OTHER ART NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		ICHIKAWA, et al., "Use of ion-exchange resins to prepare 100 µm-sized microcapsules with prolonged	
		drug-release by the Wurster process" International Journal of Pharmaceutics 216:67-76 (2001).	
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Examiner's	Date Considered	
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<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.